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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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The following is a summary of *Safety and Effectiveness for the albahealth PAS Wrap System*.

The PAS Wrap System is composed of two leg wrap members constructed of an inflatable bladder enclosed in a fabric cover with an outside surface that will accept a Velcro fastener hook strip. Extending from one side of this enclosed bladder is an elastic fabric cut to conform to the shape of the calf area of the leg. This fabric is wrapped around the back of the calf and is attached to the other side of the bladder with a Velcro fastener. The Velcro fastener allows for a tight fit on various size legs. The inflation pump is attached to the bladders and is energized. The bladder on each leg is alternately inflated and deflated to yield approximately 65mm Hg pressure on the calf area of the leg. This pressure causes pooled blood to be expelled from the calf and to proceed toward the heart. This helps to prevent embolisms from forming in the calf area.

The **albahealth** PAS Wrap System is applied to the leg in the same manner as the Jobst Athrombic Pump System 2000. It uses the **albahealth** Pulsatile Anti-Embolism System pump to supply the pressure to the calf of the leg at the same values as the PAS-Pulsatile Anti-Embolism System. The indications for use and the contraindication are listed separately in this application.

Following is a summary of articles showing the benefits of this device and also MDR's and adverse experience reports.